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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,610	09/14/2006	Gillian Smith	03981/0203467-US0	6340

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EXAMINER	
PAK, YONG D	
ART UNIT	**PAPER NUMBER**
1652	
MAIL DATE	**DELIVERY MODE**
12/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,610	SMITH ET AL.	
	Examiner	Art Unit	
	YONG D. PAK	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,15,16,32-36,38,40 and 41* is/are pending in the application.

4a) Of the above claim(s) *1,32-34 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,16,35,36,40 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 of PCT/GB04/01453.

The amendment filed on August 20, 2009, amending claim 35, has been entered.

Claims 1, 15-16, 32-36, 38, and 40-41 are pending. Claims 1, 32-34, and 38 are withdrawn. Claims 15-16, 35-36, and 40-41 are under consideration.

Response to Arguments

Applicant's amendment and arguments filed on August 20, 2009, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied.

Claim Rejections - 35 USC § 112

In view of the amendment of claim 35, the rejection of claims 35 and 15-16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been **withdrawn**.

Claim Rejections - 35 USC § 103

Claims 15-16, 35-36, and 40-41 remain rejected under 35 U.S.C. 103(a) as being unpatentable Bickers et al., Janmohamed et al., Nelson et al., and Rylander et al.

Claims 15-16 and 35 are drawn to a method of assessing the ability of a skin treatment to modulate CYP2S1 level, wherein upon administering said skin treatment, CYP2S1 level is increased or decreased. Claims 36 and 40-41 are drawn to a method of determining whether a subject is likely to respond to a skin treatment with a chemical that is metabolized by CYP2S1 by comparing the level of CYP2S1 in a first sample of a diseased skin and a second sample of a non-diseased skin from a subject.

Bickers et al. (*J Clin Invest* **62** (1978), p. 1061-1068 - form PTO-892) discloses a method of a method of assessing the ability of a skin treatment to modulate CYP level or whether a subject is likely to respond to a skin treatment comprising of coal tar by measuring said enzyme's level (page 1062). With this teaching at hand, one having ordinary skill in the art would have looked to other known cytochrome P450 enzymes whose genes have been cloned in order to better measure or detect cytochrome P450 enzyme in tissue.

The difference between the reference of Bickers et al. and the instant claims is that the reference of Bickers et al. does not disclose a method of using CYP2S1 as the cytochrome P450 enzyme.

Janmohamed et al. (Biochem Pharmacol 62 (2001), pp. 777–786 - form PTO-892) discloses the expression of members of the CYP 2 family in human skin (abstract, pages 778-781). Janmohamed et al. discloses that several mammalian CYP families have been identified and cites Nelson et al. (Arch Biochem Biophys. 1999 Sep

1;369(1):1-10 – form PTO-892) which discloses a UNIGENE of CYP2S1 (page 778 of Janmohamed et al. and page 2 of Nelson et al). Rylander et al. (*Biochem Biophys Res Commun* **281** (2001), pp. 529–535 – form PTO-1449) discloses isolation and cloning of a CYP2S1, method of detecting CYP2S1 using an antibody and detecting CYP2S1 mRNA levels(pages 530, 532 and 533).

Therefore, combining the above references, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine which of the CYP proteins disclosed by Nelson et al. are expressed in human skin and (1) assess the ability of a skin treatment, such as coal tar, to modulate CYP or CYP2S1, wherein upon administering said skin treatment, CYP or CYP2S1, level is increased or decreased, and (2) determine whether a subject is likely to respond to a skin treatment, such as coal tar, by comparing the level of a CYP, such as the CYP2S1 of Rylander et al., in a first sample of a diseased skin and a second sample of a non-diseased skin from a subject.

One of ordinary skill in the art at the time the invention was made would have been motivated to substitute the CYP protein used in Bickers et al. with other CYP proteins which have been cloned, such as the CYP2S1 enzyme of Rylander et al., allowing easier and more specific detection of CYP levels in tissue. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for success because Janmohamed et al. teaches expression of several CYP 2 family proteins in skin, Rylander et al. teaches the cDNA sequence encoding a CYP2S1 protein and how to detect the enzyme's level in tissue using antibodies or measuring

CYP2S1 mRNA, and Northern blot analysis of the distribution of proteins in human tissue is well known and taught by Rylander et al and Janmohamed et al.

Therefore, Bickers et al., Janmohamed et al., Nelson et al., and Rylander et al. render claims 15-16, 35-36, and 40-41 *prima facie* obvious to those skilled in the art.

In response to the previous Office Action, applicants have traversed the above rejection.

Applicants argue that the claims are not obvious over the cited references because none of the references disclose or suggest that CYP2S1 levels vary between diseased and non-diseased skin nor expression of CYP2S1 in skin and such knowledge was needed to arrive at the claimed invention. Examiner respectfully disagrees. Bickers et al. discloses a P450 with varying levels of in diseased and non-diseased skin and a method of a method of assessing the ability of a skin treatment to modulate said CYP or whether a subject is likely to respond to a skin treatment comprising of coal tar by measuring said enzyme's level (page 1062). Janmohamed et al. discloses expression of several mammalian members of the CYP 2 family in human skin (abstract, pages 778-781) and cites Nelson et al. (Arch Biochem Biophys. 1999 Sep 1;369(1):1-10 – form PTO-892) which discloses a UNIGENE of CYP2S1 (page 778 of Janmohamed et al. and page 2 of Nelson et al). With these teachings at hand, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the CYP protein used in Bickers et al. with other CYP proteins which have been cloned, such as the CYP2S1 enzyme of Rylander et al., by determining which of the finite number of CYP proteins disclosed by Nelson et al. are expressed in

human skin and have varying levels in diseases and non-diseased skin, in an attempt to allow easier and more specific detection of CYP levels in tissue as a person with ordinary skill has a good reason to pursue the known options within his or her technical grasp. MPEP 2145 states that “An "obvious to try" rationale may support a conclusion that a claim would have been obvious where one skilled in the art is choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success. " [A] person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1397 (2007).”. In the instant case, one skilled in the art would be choosing form a finite number of identified, predictable solutions, CYPs disclosed by Nelson et al., Janmohamed et al., and Rylander et al. One skilled in the art would have had a reasonable level of success since Janmohamed et al. teaches expression of several CYP 2 family proteins in skin, Rylander et al. teaches the cDNA sequence encoding a CYP2S1 protein and how to detect the enzyme's level in tissue using antibodies or measuring CYP2S1 mRNA, and Northern blot analysis of the distribution of proteins in human tissue is well known and taught by Rylander et al and Janmohamed et al.

Hence the rejection is maintained.

Conclusion

Claims 15-16, 35-36, and 40-41 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Yong D Pak/
Primary Examiner, Art Unit 1652